JUL 12 2002

K022109

10. 510(k) Summary

as required by 807.92

1. Company Identification

Submitter name : EIZO NANAO CORPORATION
Address :153. Shimokashiwano. Matto. Ishikawa. 924-8566. Japan
Tel :+81-76-274-2468
Fax :+81-76-274-2484

2. Official Correspondent

Hiroaki Hashimoto (Mr.)
Manager. engineering management section

3. Date of Submission

February 4. 2002

4. Device trade name

20.8 inch class monochrome LCD monitor

5. Common name

Monitor

6. Classification

Medical displays were classified in class II (21 CFR 890.2050)

7. Intended use
The FC-2091 monochrome LCD monitor is intended to use in displaying for diagnosis of X-ray or MRI etc.

8. Predicate Device

Manufacturer: Totoku Electric Co.. Ltd.
Device name: MONOCHROME PERFECTLY FLAT PANEL DISPLAYS
Model name : ME311L : 510(k) No.: K012099)
Gray scale tones: 1021tones

9. Comparison of technological characteristics between new device and predicate device

Please refer to the attachment Appendix.3.

Comparison table with predicate device

Item	FC-2091 (EIZO)	ME311L (Totoku)
510(k) number	-	K012099
Technological characteristics		
LCD inches	20.8 inches	20.8 inches
LCD surface	AG coating	AG coating
Display area	423.9[mm](H) x 318[mm](V)	423.9[mm](H) x 318[mm](V)
Input signal (Digital)	TMDS (Single Link)	GVIF (10214-1210VE)
Screen resolution	2048 x 1536 or 1536 x 2048	2048 x 1536 or 1536 x 2048
Gray-scale display	1531 tones (10.5bit) (In accordance with DICOM Part 14)	1021 tones
Luminance	Max.650[cd/m²]	600[cd/m²] or more
Luminance calibration	・Software (Option) ・Photo-sensor (Option) [model DTP92:X-rite] ・Protection panel (Option)	・Software (Option) ・Photo-sensor (Option) [model DTP92:X-rite] ・Photo-sensor holder (Option)
Connector	DVI-D x1 USB 1up. 2down Serial (mini DIN 6pin) Serial (D-sub 9pin) Sensor serial port: (mini DIN 8pin)	D-sub (9pin) x2 USB 1up. 2down
Dimensions (W x H x D [mm])	474 x 368 x 84[mm] (Approx.)	486 x 480 x 250[mm] (Approx.)
Weight [kg]	9.5kg	11kg
Power	AC100-120V/200-240V 50/60Hz Max.95W	AC100-240V 50/60Hz Normally approx.70W
Complied Standard	IEC60601-1 UL2601-1 CSA No.601-1 MDD/CE (EN60601-1/EN60601-1-2) FCC class A VCCI class A	Safety: IEC60601-1 UL2601-1 CSA No.601-1 MDD/CE (EN60601-1) FDA510(k) EMC: FCC class A VCCI class A BSMI (CNS13438/C6357)

Eizo's FC-2091 is different compared to a predicate device. Totoku ME311L in difference of built-in circuit of power supply instead of AC adapter. Looking at two models' outside, the shape of stand and connector and the number of connectors. However, the basic structure of the both models are the same in terms of consisting of LCD display and stand, and they are capable for use in portrait mode.

Totoku ME311L adopts GVIF for transmission method for digital video signal but Eizo FC-2091 adopts TMDS method. Eizo's FC-2091 has specification of resolution in 2048[H]×1536[V] in landscape mode or 1536[H]×2048[V] in portrait mode.
Eizo' FC-2091 converts inputted 8bit video signal into 10.5bit by mean of its ASIC, and this results in displaying maximum of 1531 scales while Totoku ME311L only displays 1021 scales. Eizo's FC-2091 is able to display grayscale tones that is based on DICOM part14.

10. Description Device

<For monitor>
FC-2091 is 20.8 inches class monochrome LCD monitor for medical use.
This monitor is usually used to display for X-ray diagnosis or MRI. such as one of the medical diagnosis system. This model has specification of resolution in 2048 × 1536 or 2048 × 1536 . And this model has the USB function and optional photo-sensor DTP92 made by X-rite Incorporated. This model is certified IEC60601-1 for medical safety standard.

<For bundled digital video card>
Optional digital video card was designed exclusively for FC-2091. Type of digital video card is VR Engine MD3 by RealVision Inc. This video card for FC-2091 is sold separately. but FC-2091 support the digital video signal for only VR Engine MD3.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2002

Eizo Nanao Corp.
% Mr. Wolfram Gmelin
Technical Manager
TÜV Rheinland of North America
12 Commerce Road
NEWTON CT 06470

Re: K022109
Trade/Device Name: 20.8 inch monochrome LCD monitor (Model FC-2091)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 20, 2002
Received: June 28, 2002

Dear Mr. Gmelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K022109
Device Name: 20.8 inch Monochrome LCD Monitor

Indications for Use:

The FC-2091 monochrome LCD monitor is intended to use in displaying for diagnosis of X-ray or MRI etc.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K022109